EPA Registration No. 50233-1 Vol. 2

-Material Sent For Data Extraction-

Reg. Number: _	50233-1	
Description: _		
Material(s)	Sent to Data Extraction Contractors	
✓ New Stamp	oed Label Dated: September 1 % 2013	
☐ Notificatio	n Dated:	
□ New CSF (s	s) Dated:	
Others:		
Decision N	umber: D-483133	
Other Action/Con	nments:	
organized and clip cover sheet and n (ISC) (Room S-490 please file materia	et and attached materials in the jacket. It must be woped together, NO STAPLE. Then give the jacket with naterials to staff in the information Service Center 00). If a jacket is full or only available as an image, als in a new jacket and bring it down to the ICS. For on please call 703-605-0716.	
REVIEWER: _	Adam Heyward	
	er: <u>703-347-0274</u> Division: <u>Antimicrobials</u>	<u> </u>
Data: Santami	SS: <u>heyward.adam@epa.gov</u>	
	nur iu /ilia	

		Antimicrobial	Division/Reg	ulatory Managen	nent Branches I						
A		P	roduct Mana	ager () Dan:	on Foller					
PRODUCT RE	viewer:				RMB I	і теам	62				
Description of	Action:	1				ile Symbol/Reg N	0.:				
FQPA Action Code: Non-FQPA Action				:	PRIA Action Co						
Decision No.	33	Submission 94	,		Fee for Service I	/					
		МО	NTH	DAY		YEAR					
APPLICATION	N DATE					2013					
EPA PIN DAT	E					2013					
REVIEWER A	SSIGNED DATE	3		***************************************	and the second						
DATE DUE TO	PM.		1		2013						
A TOTAL PROPERTY.	JT OF AGENCY	1		24	2013						
Type of Data:	Product Chemistry	Acute Toxicology	Efficacy	Environmental Fate	Ecological Effects	Chronic Toxicology	Exposure				
Comments:		and the labe		s package is	add the o	one Ted had	Isce				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

SEP 18 2013

Ted Wallace Polar Equipment, Inc. 12881 Foothill Lane Saratoga, CA 95070

SUBJECT: Polar Pure Water Disinfectant

EPA Registration Number: 50233-1 Application Date: August 15, 2013 Date of Email Receipt: August 15, 2013

Dear Mr. Wallace:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

The Agency has no objections to you modifying your Precautionary Statements, Storage and Disposal Statements, and removing the word "safe" from your label.

General comments:

A stamped copy of the label is enclosed for your records. This labeling supersedes all previously accepted ones. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you must distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR § 152.3. A copy of the EPA stamped labeling has been placed in the subject product regulatory file for future reference.

Should you have any questions or comments concerning this letter, please contact me via email at: <u>fuller.demson@epa.qov</u> or by telephone at (703) 308-6224 during the hours of 9:00 am to 5:30 pm EST.

Sincerely,

Demson Fuller

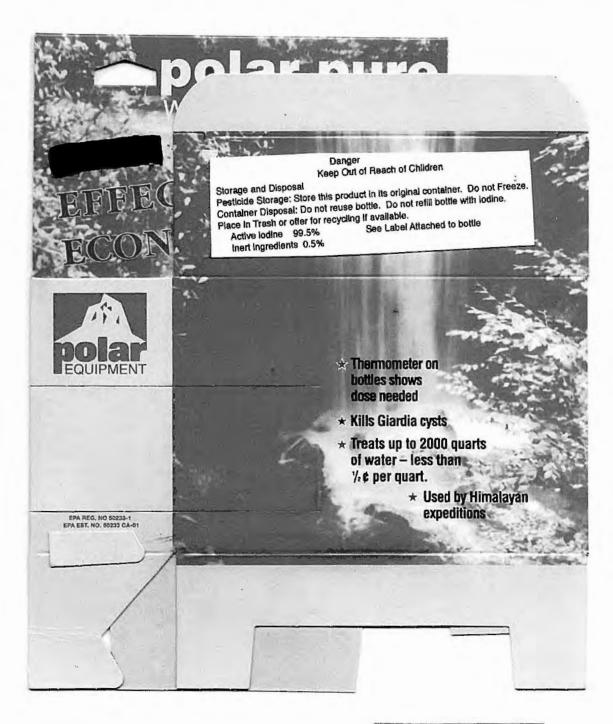
Acting Product Manager (32)

Regulatory Management Branch II

Antimicrobials Division (7510P)

Enclosure: Stamp label

Polar Pure display box front and side panel with modifications (explained in cover letter, page 1)



ACCEPTED

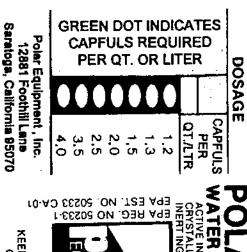
SEP 18 2013

Under the Federal Insecticide, Fungicide, and Rodenticide, Act as rangined, for the pesticide, registered under EPA Reg. No. 50:233—/

Polar Pure display box back and side panel with modifications (explained in cover letter, page 1)









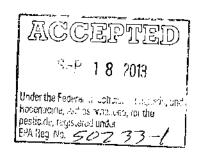
DESTROYS WATER-BORNE PATHOGENS (INCLUDING GIARDIA) WHEN USED AS DIRECTED DIRECTIONS FOR USE

Fill this iodine bottle with water and shake. Solution ready to use in one hour. Pour required capfuls (see DOSAGE table) of solution into a quart of drinking water (double dosage for cloudy water). Let stand 20 minutes before use; after this, flavoring may be added. To destroy Giardia cysts, drinking water must be 20°C (68°F) minimum (water can be warmed in sun, or add hot water to cold). Refill iodinebottle with water after each use so solution will be ready for use one hour later. Crystals in bottle make enough solution to treat 2000 quarts drinking water. Do NOT freeze. Do not reuse bottle, discard safely.

• Solution effective as long as any iodine

- Solution effective as long as any iodine crystals are visible.
- Particle trap prevents crystal loss.
 Solution not affected by age, air or temperature.

Use solution only; crystals harmful if swallowed and may damage skin or eyes on contact. FIRST AID: Internal, drink starch in water; for skin and eyes flush with water. Call a physi-





August 15, 2013

US Environmental Protection Agency Office of Pesticide Programs Document Processing Desk (7504P) Room S-4900 1200 Pennsylvania Ave., NW Washington, DC 20460-0001

ATTENTION: Demson Fuller Acting Product Manager, Team 32

Product name -- Polar Pure Water Disinfectant

Ingredient -- lodine

EPA Reg. Number 50233-1

Submitting for acceptance with requested modifications, master labels for Polar Pure display box.

Number of pages - 6

Page 1 of 6 -- Cover letter

Page 2 of 6 -- Master label for (original) front and side panel of Polar Pure display box

Page 3 of 6 -- Master label for front and side panel of Polar Pure display box - with modifications**

Page 4 of 6 -- Master label for (original) back and side panel of Polar Pure display box

Page 5 of 6 -- Master label for back and side panel of Polar Pure display box - with modifications**

Page 6 of 6 -- Master label for Polar Pure bottle

^{**} Master label for display box (page 3 and 5) includes requested modifications --Danger, and Keep out of reach of children statement
Storage and Disposal statement. Ingredients statement. Instructions to see label on bottle
Removal of the word "safe" from front and back of box.
Removal of mailing address of Polar Equipment, Inc. on side of box.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 17, 2013

OFFICE OF CHEMICAL SAFETY AND POLLUTION **PREVENTION**

ROBERT WALLACE POLAR EQUIPMENT INC 12881 FOOTHILL LANE SARATOGA, CA 95070

PRODUCT NAME: POLAR PURE

COMPANY NAME: POLAR EQUIPMENT INC

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 50233-1 EPA RECEIPT DATE: 08/26/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 32, at (703) 308-8062.

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division

Fee for Service

{940192"~

This package includes the following	for Division
 New Registration Memore Amendment Studies? □ Fee Waiver? volpay % Reduction: 	● AD ○ BPPD ○ RD Risk Mgr. 32
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	50233-1 9/17/2013
This item is NOT subject to Action Code: Requested: Granted: Amount Due: \$	Parent/Child Decisions:
Inert Cleared for Intended Use Reviewer: Remarks:	Uncleared Inert in Product Date:



August 15, 2013

US Environmental Protection Agency Office of Pesticide Programs Document Processing Desk (7504P) Room S-4900 1200 Pennsylvania Ave., NW Washington, DC 20460-0001

ATTENTION: Demson Fuller Acting Product Manager, Team 32

Product name -- Polar Pure Water Disinfectant

Ingredient -- Iodine

EPA Reg. Number 50233-1

Submitting for acceptance, master labels for Polar Pure Water Disinfectant bottle and Polar Pure display box.

Number of pages - 4

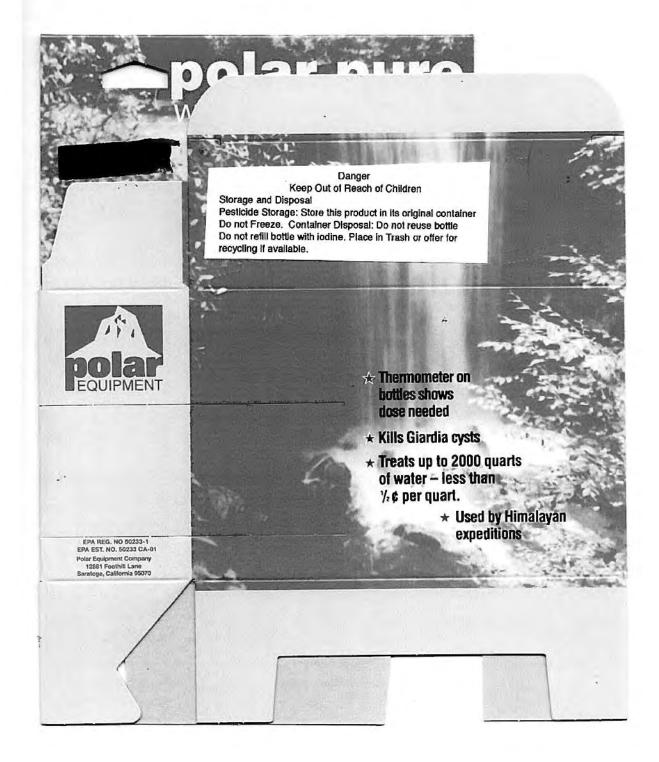
Page 1 of 4 -- Cover letter

Page 2 of 4 -- Master label for (original) Polar Pure display box

Page 3 of 4 -- Master label for Polar Pure display box - with modifications*

Page 4 of 4 -- Master label for Polar Pure bottle

* Master label for display box (page 3) includes modifications ---Danger, and Keep out of reach of children statement Storage and Disposal statement Removal of the word "safe"



ATT00001

```
On Sep 13, 2013, at 7:37 AM, Fuller, Demson wrote:
> Hi Ted,
> Your dad sent a fax earlier this week proposing some modifications to the label you originally submitted. I took a look at what was proposed and it is okay. Can
you revise the original label and submit that back to us electronically?
> Thanks!
> Demson
  ----Original Message----
  From: Polar Equipment [mailto:questions@polarequipment.com]
  Sent: Tuesday, September 10, 2013 12:34 PM
  To: Fuller, Demson
 Cc: Mendelsohn, Mike; Heyward, Adam
Subject: Re: Modifications for Polar Pure box
> Dear Demson,
  Do you have any updates of the status of our application?
  Thank you.
  Ted Wallace, Polar Equipment, Inc.
  On Aug 26, 2013, at 11:30 AM, Fuller, Demson wrote:
>> Hi Ted,
>> Just an fyi, I am still processing the application you submitted and hopefully will be finished by the end of this week.
>> Let me know if you have any questions.
>>
>> Demson
>>
>> ----Original Message-----
>> From: Polar Equipment [mailto:questions@polarequipment.com]
>> Sent: Friday, August 16, 2013 12:23 AM
>>> To: Fuller, Demson
>>> Cc: Mendelsohn, Mike; Heyward, Adam
>> Subject: Re: Modifications for Polar Pure box
>>
>> Dear Demson,
>>
>> Attached is the Polar Pure box label modification with your requested addition of
the EPA address.
>> Thank you,
>> Ted Wallace, Polar Equipment, Inc.
>>
>>
```

Mendelsohn, Mike

> Michael Mendelsohn

> Senior Regulatory Specialist

From: Mendelsohn, Mike Sent: Thursday, August 15, 2013 2:35 PM To: 'Polar Equipment' Cc: Fuller, Demson Subject: RE: Modifications for Polar Pure box Thanks Ted. 8 pt font is fine. Michael Mendelsohn Senior Regulatory Specialist Antimicrobials Division (7510P) / Office of Pesticide Programs U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington DC 20460 (703) 308-8715 (703) 463-7302 Blackberry (703) 305-5620 (fax) ----Original Message----From: Polar Equipment [mailto:questions@polarequipment.com] Sent: Thursday, August 15, 2013 2:09 PM To: Mendelsohn, Mike Subject: Re: Modifications for Polar Pure box Thank you Mike. We will work on this and send a file to you. Is there a specific font size for the language on the box? The font size in #1 is 8pt. Ted Wallace, Polar Equipment, Inc. On Aug 14, 2013, at 1:56 PM, Mendelsohn, Mike wrote: > Ted, > Thanks. You will need to use the box modification # 1. I suggest you add a cover page to your label that indicates it is a master label. This page should state the product name, the ingredient statement, Keep Out of Reach of Children statement, Danger signal word, and registration number. It should also indicate Master Label and say page 1 of 3. The next two pages should be the bottle label and the box label. The bottle label page should state that at the bottom and page 2 of 3. The box label page should indicate that and page 3 of 3. The box label may need an additional page to show the carton unfolded so that all the text can be seen. My understanding is that you will be selling the bottle in the box. Page 1 simply designates that what you are submitting for acceptance is a master label that includes both the box and the bottle labels. > > Best Regards, >

> Antimicrobials Division (7510P) / Office of Pesticide Programs U.S.

```
> Environmental Protection Agency
> 1200 Pennsylvania Avenue NW
> Washington DC 20460
> (703) 308-8715
> (703) 463-7302 Blackberry
> (703) 305-5620 (fax)
>
>
> ----Original Message-----
> From: Polar Equipment [mailto:
> Sent: Friday, August 09, 2013 12:43 PM
> To: Mendelsohn, Mike
> Cc: Fuller, Demson
> Subject: Re: Modifications for Polar Pure box
> Dear Mike,
> I am attaching two "mock ups" of the Polar Pure box with the storage and disposal language.
One version (#1) is as you sent to us. Version #2 is the same language but the arrangement
is modified slightly in order to make it possible to fit it all of the wording on a stamp.
We are limited on the size of the stamp. Is it ok to use version #2 or does it have to be
like you sent (#1).
>
> I contacted our bottle printer and asked them to send a PDF of our current bottle label and
am attaching that as well. It is the same version that you have.
> Let me know if version #2 is ok to use on our remaining boxes. I can send a separate e-
mail to you that includes just the labels for the bottle and the box if you would like, once
I know which box version is preferred.
>
> Thank you,
> Ted Wallace, Polar Equipment, Inc.
> <Polar Pure box modif. #1 pdf.pdf>
> <Polar Pure box modif. #2pdf.pdf>
> <polar221.pdf>
> On Aug 5, 2013, at 1:20 PM, Mendelsohn, Mike wrote:
>> Thanks Ted. We will need you to provide a master label that includes both the box and the
bottle label. For the box, you should add the text to the box as you had done previously. I
have attached a copy of the 1997 bottle label from our system and a modified version of the
new language for the box label based on our last teleconference. I am working with Demson and
suggest you wait to have the stamp made until you have final acceptance of the amendment.
>>
55
>> Michael Mendelsohn
>> Senior Regulatory Specialist
>> Antimicrobials Division (7510P) / Office of Pesticide Programs U.S.
>> Environmental Protection Agency
>> 1200 Pennsylvania Avenue NW
>> Washington DC 20460
>> (703) 308-8715
>> (703) 463-7302 Blackberry
>> (703) 305-5620 (fax)
```

```
>>
>>
>>
>> ----Original Message-----
>> From: Polar Equipment [mailto:questions@polarequipment.com]
>> Sent: Monday, August 05, 2013 2:11 PM
>> To: Mendelsohn, Mike
>> Subject: Modifications for Polar Pure box
>>
>> Dear Mike,
>>
>> Per our phone conversation on Aug. 1, 2013, I am attaching wording for a stamp to include
on our remaining display boxes for instructions for bottle disposal. The attachment includes
the original wording and the modification. Please review and let me know if the modification
is correct or if any other changes are needed. Upon your approval, we will have a new stamp
made and include the instructions on our remaining boxes.
>> Let me know if you have any other questions.
>>
>> Thank you,
>> Ted Wallace, Polar Equipment, Inc.
>> (408)773-9201 (h)
>> (408)497-5891 (c)
>>
>> <50233-1-2 1997 Label.pdf><50233-1 Box.pdf>
```

17

3

Mendelsohn, Mike

From:

Mendelsohn, Mike

Sent:

Tuesday, July 16, 2013 4:14 PM

To:

'Polar Equipment'

Cc: Subject: Heyward, Adam; Fuller, Demson RE: Polar Pure iodine registration

Ted.

Thank you for your note. Subsequent to my conversation with your father and your email below, we have determined that section III of my June 13, 2013 letter is not applicable to Polar Pure. Sections I and II of the letter still need to be addressed. Please let me know if you have any further questions.

Best Regards,

Michael Mendelsohn
Senior Regulatory Specialist
Antimicrobials Division (7510P) / Office of Pesticide Programs U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 463-7302 8lackberry
(703) 305-5620 (fax)

----Original Message----

From: Polar Equipment [mailto:questions@polarequipment.com]

Sent: Sunday, July 07, 2013 11:49 PM

To: Mendelsohn, Mike

Subject: Polar Pure iodine registration

Dear Mike,

You spoke with my father, Bob Wallace regarding the letter you sent to him of June 13, 2013 (original letter date Sept. 11, 2012) and our product Polar Pure EPA registration number 50233-1.

In section III (Other Information) of the above letter, you refer to the RED of July 27, 2006 and a certified letter that was sent to all registrants. Bob does not remember receiving a letter by certified mail in 2006 regarding this subject. I have checked the regulations website using the docket id number you refer to in the above letter but am not sure what forms are required.

Would you please reply to this e-mail and include a link to the exact form(s) and instructions that you require so that we can complete this part of the registration process.

Thank you,

Ted Wallace, Polar Equipment, Inc.

United States Environmental Protection

		Agency Washingto	on, D.C. 20460	// (- / /		OND Apploval 2070-174		
		DATA CALL-IN	RESPONSE					
INSTRUCTIONS: Please type Use additional sheet(s) if neces		read carefully the attached instruction	ons and supply the information requeste	d on this form.		•		
1. Company Name and Address POLAR EQUIPMENT INC 12881 FOOTHILL LANE SARATOGA, CA 95070	С	2. Case # and Nam 3080 lodine, K Chemical # and I lodine		i i	Date and Type of DCI and Number 12-Oct-1993 GENERIC ID # GDCI-046905-17430			
PA	5. I wish to	6. Generic Data		7. Product Sp	pecific Data			
r .uduct Registration	cancel this product regis- tration volun- tarily	6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	I agree to sa requirements	duct is an MUP and atisfy the MUP is on the attached d "Requirements Registrant's	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."		
50233-1					N.A.	N.A.		
Certification I certify that the knowingly false or misleading states.	ne statements made or tatement may be punis	on this form and all attachments are tro shable by fine, imprisonment or both	ue, accurate, and complete. I acknowle under applicable law.	edge that any	9. Date			
Signature and Title of Company	's Authorized Represe	entative						
10. Name of Company					11. Phone Number	19		

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please typuse additional sheet(s) if nec	pe or print in ink. Please read carefully t ressary.	he attached instructions and	sup	oly th	e info	ıma	tion requested on this fo	orm.			
1. Company Name and Address POLAR EQUIPMENT INC 12881 FOOTHILL LANE SARATOGA, CA 95070		Case # and Name 3080 lodine, Kl Chemical # and Name lodine		046	905				Date and Type of DCI and Number 12-Oct-1993 GENERIC ID # GDCI-046905-17430		
Guideline .quirement Number	5. Study Title		PROFOCOL		ogres eport		6. Use Pattern		7. Test Substance	8. Time Frame (Months)	9. Registran Response
			Ŀ								
61-1	Chemical Identity		N				K, D, M, A, J, E, F, I	-		12	
61-2a	Begin. mat. & mnfg. proc		N				K, D, M, A, J, E, F, l	-		12	
61-2b	Discussion of Impurities		N				K, D, M, A, J, E, F, I	-		12	
62-1	Preliminary Analysis		N ;				K, D, M, A, J, E, F, I	-		12	:
62-2	Certification of limits		N				K, D, M, A, J, E, F, l	.		12	
j	Analytical Method		N				K, D, M, A, J, E, F, L	-		12	
63-2	Color		N				K, D, M, A, J, E, F, l	.		12	
63-3	Physical State		N				K, D, M, A, J, E, F, l	.		12	
63-4	Odor		N				K, D, M, A, J, E, F, l	-		12	
63-5	Melting Point		N				K, D, M, A, J, E, F, l	-		12	
63-7	Density		Ŋ				K, D, M, A, J, E, F, l	-		12	
	1 hat the statements made on this form an g statement may be punishable by fine, i					ompl	ete. I acknowledge tha	t any	11. Date		
Signature and Title of Company's Authorized Representative											
								13. Phone Number		20	

United States Environmental Protection

Agency Washington, D.C. 20460

	REQUIREMENT	S STATUS AND REGI	ST	KAſ	NT'S	S KI	ESPONSE			
INSTRUCTIONS: Please ty Use additional sheet(s) if ne	pe or print in ink. Please read careful cessary.	ly the attached instructions and	sup	ply th	e info	orma	tion requested on this f	orm.		
Company Name and Add POLAR EQUIPMENT 12881 FOOTHILL LA SARATOGA, CA 95	Case # and Name 3080 lodine, KI Chemical # and Name lodine		048	905			12-Oct-1993 GENERIC			
4. Guideline Requirement Number	5. Study Title		P R O T O C O	R	rogre:	ts	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrar Response
			L	1	2	3				
63-8	Solubility		N				K, D, M, A, J, E, F, I	-	12	
63-9	Vapor Pressure		N				K, D, M, A, J, E, F, I	-	12	
63-10	Dissociation Constant		N				K, D, M, A, J, E, F, I	-	12	
63-12	рН		N				К, D, M, A, J, E, F, I	-	12	
63-13	Stability		N				K, D, M, A, J, E, F, I	_	12	
71-1a	Acute avian oral quail/duck		N				K, D, M, A, J, E, F, I	-	12	
71-2a	Acute avian diet. quail		N				K, D, M, A, J, E, F, I	-	12	
72-1c	Fish toxicity rainbow trout		N				K, D, M, A, J, E, F, I	-	12	
72-2a	Invertebrate toxicity		N				K, D, M, A, J, E, F, I	-	12	
72-3a	Estu/mari tox. fish		N				K, D, M, A, J, E, F, I	-	12	
72-3b	Estu/mari tox. mollusk		N				K, D, M, A, J, E, F, I	-	12	
72-3c	Estu/mari tox. shrimp		N				K, D, M, A, J, E, F, I	-	12	
Initial to indicate certification (full text of certification is on	as to information on this page page one).							Date		21

OMB Approval 2070-174

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 2. Case # and Name 3. Date and Type of DCI and Number 1. Company Name and Address 3080 lodine, KI 12-Oct-1993 POLAR EQUIPMENT INC 12881 FOOTHILL LANE Chemical # and Name 046905 **GENERIC** lodine SARATOGA, CA 95070 ID # GDCI-046905-17430 6. Use 7. Test 8. Time 9. Registrant Guideline 5. Study Title Progress Pattern Substance Frame Response .quirement Reports (Months) Number 0 ě 2 3 K, D, M, A, J, E, F, L 24 Acute oral toxicity in rats Ν 81-1 Acute dermal toxicity in rabbits or rats K, D, M, A, J, E, F, L 24 81-2 K, D, M, A, J, E, F, L Acute inhalation toxicity in rats Ν 24 81-3 12 Primary eye irritation in rabbits K, D, M, A, J, E, F, L 81-4 IN 12 Primary dermal irritation K, D, M, A, J, E, F, L 81-5 K, D, M, A, J, E, F, L 12 Dermal sensitization Ν 81-6 90-day dermal-rodent K, D, M, A, J, E, F, L 24 82-1a 90-day feeding-rodent K, D, M, A, J, E, F, L 24 K, D, M, A, J, E, F, L Teratogenicity - rat 24 83-3a N Other genotoxic effects K, D, M, A, J, E, F, L 12 84-4 Ν K, D, M, A, J, E, F, L 12 Gene mutation-ames 84-2a K, D, M, A, J, E, F, L Struct, chrom, aberration 12 84-2b Initial to indicate certification as to information on this page Date 22 (full text of certification is on page one).

Initial to indicate certification as to information on this page

(full text of certification is on page one).

OMB Approval 2070-174

23

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE INSTRUCTIONS; Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 2. Case # and Name 3. Date and Type of DCI and Number 1. Company Name and Address POLAR EQUIPMENT INC 3080 lodine, KI 12-Oct-1993 12881 FOOTHILL LANE Chemical # and Name 046905 **GENERIC** lodine SARATOGA, CA 95070 ID# GDCI-046905-17430 4. Guideline 6. Use 7. Test 8. Time 9. Registran 5. Study Title Progress Requirement Pattern Substance Frame Response Ö Reports Number (Months) 2 3 Foliar residue dissipation K, D, M, A, J, E, F, L 24 132-1a K, D, M, A, J, E, F, L 132-1b Soil residue dissipation 24 K, D, M, A, J, E, F, L Dermal passive dosimetry expo 24 133-3 24 Inhal, passive dosimetry expo-K, D, M, A, J, E, F, L 133-4 K, D, M, A, J, E, F, L 12 Estimation Of Dermal Exposure - Indoor 233 K, D, M, A, J, E, F, L 234 Estimation Of Inhalation Exposure - Indoor 12

Date

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 3080 lodine, Kl **DCI Number:** GDCI-046905-17430

Key:

Use Categories Key:

Terrestrial food crop

F - Aquatic nonfood industrial use L -

Indoor food use

L Aquatic food crop

J - Forestry use

M - Indoor nonfood use

E - Aquatic nonfood outdoor use K - Residential

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Data for 61-2(b), 62-1 and 62-2 is required but will bewaived if USP or ACS grade of this chemical is used.

Guideline series 61, 62, and 63 data on iodine WILL NOT beaccepted for iodine complexes or potassium iodide.

Guidelines 63-14 to 63-21 will not be required until Phase 5of re-registration.

All testing for guidelines 71-1 through 72-3, may bedone on todine only. There is no need to do separate studiesfor each iodine complex and or potassium iodide. In addition, guidelines 72-3a, 72-3b, and 72-3c are required only for those chemicals with once-through coolingtower or secondary oil recovery injection water uses.

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 3080, lodine, KI

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
50233	POLAR EQUIPMENT INC		12881 FOOTHILL LANE	SARATOGA	CA 95070
4959	WEST AGRO INC		11100 N. CONGRESS AVE.	KANSAS CITY	MO 64153
1677	ECOLAB INC.		370 NORTH WABASHA STREET	ST. PAUL	MN 55102
15118	BALTIMORE AIRCOIL COMPANY INC	DELTA ANALYTICAL CORP	7910 WOODMONT AVE STE 1000	BETHESDA	MD 20814
64005	PUR WATER PURIFICATION PRODUCTS, INC.		8700 MASON MONTGOMERY ROAD	MASON	OH 45040
4/0/1	H & S CHEMICALS DIVISION		90 BOROLINE ROAD	ALLENDALE	NJ 07401
35917	HYBRID TECHNOLOGIES CORPORATION	REGWEST COMPANY, LLC	8203 WEST 20TH STREET, SUITE A	GREELEY	CO 806344696

OMB Approval 2070-174

26

11. Phone Number

United States Environmental Protection Agency Washington, D.C. 20460

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.

Signature and Title of Company's Authorized Representative

10. Name of Company

Use additional sheet(s) if necessary. 2. Case # and Name 1. Company Name and Address 3. Date and Type of DCI and Number POLAR EQUIPMENT INC 3080 Iodine, KI 04-Jan-1994 12881 FOOTHILL LANE Chemical # and Name 046905 **GENERIC** SARATOGA, CA 95070 lodine ID# GDCI-046905-17524 6. Generic Data 7. Product Specific Data PA. 5. I wish to **Product** cancel this Registration product regis-6a. I am claiming a Generic 6b. I agree to satisfy Generic 7a. My product is an MUP and 7b. My product is an EUP and tration volun-Data Exemption because I Data requirements as indicated I agree to satisfy the MUP Lagree to satisfy the EUP tarily obtain the active ingredient on the attached form entitled requirements on the attached requirements on the attached from the source EPA regisform entitled "Requirements "Requirements Status and form entitled "Requirements tration number listed below. Registrant's Response." Status and Registrant's Status and Registrant's Response." Response." 50233-1 N.A. N.A. 8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any 9. Date knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

United States Environmental Protection

Agency Washington, D.C. 20460

REQUIREMENTS	STATUS AND	REGISTRANT'S RESPONSE
--------------	------------	-----------------------

	TEQUIE: TE	BIATOS AND REGI	,,,	ACXI.	1 1 1	, 10	ESI ONSE				
INSTRUCTIONS: Please typ Use additional sheet(s) if neo	pe or print in ink. Please read carefully the sessary.	ne attached instructions and	supj	oly th	e info	oma	tion requested on this fo	orm.			
1. Company Name and Add	ress	2. Case # and Name						3.	Date and Type of DCI and Nu	mber	
POLAR EQUIPMENT	INC	3080 Iodine, Kl							04-Jan-1994		
12881 FOOTHILL LAN		Chemical # and Name lodine		046	905				GENERIC		
SARATOGA, CA 950	SARATUGA, CA 95070								ID# GDCI-046905-17524		
Guideline _quirement Number	5. Study Title		PROTO		Progress Reports		6. Use Pattern	7. Test Substance		8. Time Frame (Months)	9. Registrant Response
			00-	1 2 3		3	1				
											
61-1	Chemical Identity		Ŋ				K, D, M, A, J, E, F, L	-			
61-2a	Begin. mat. & mnfg. proc		N				K, D, M, A, J, E, F, L				
61-2b	Discussion of Impurities		N				K, D, M, A, J, E, F, L				
62-1	Preliminary Analysis		N				K, D, M, A, J, E, F, L				
62-2	Certification of limits		N				K, D, M, A, J, E, F, L				
3	Analytical Method		N				K, D, M, A, J, E, F, L			i	
63-2	Color		N				K, D, M, A, J, E, F, L				
63-3	Physical State		N				K, D, M, A, J, E, F, L				
63-4	Odor		N				K, D, M, A, J, E, F, L	.			
63-5	Melting Point		N				K, D, M, A, J, E, F, L				
63-6	Boiling Point		N				K, D, M, A, J, E, F, L				
		•									
10. Certification I certify the knowingly false or misleading	nat the statements made on this form and statement may be punishable by fine, in	d all attachments are true, ac nprisonment or both under a	cura	ite, a cable	nd co law	omp!	ete. I acknowledge that	any	11. Date		
Signature and Title of Compa	any's Authorized Representative			_							27
12. Name of Company									13. Phone Number		21
									•		

OMB Approval 2070-174

United States Environmental Protection Agency Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

(full text of certification is on page one).

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number 3080 lodine, KI 04-Jan-1994 POLAR EQUIPMENT INC Chemical # and Name 046905 **GENERIC** 12881 FOOTHILL LANE lodine SARATOGA, CA 95070 ID# GDCI-046905-17524 6. Use 7. Test 8. Time 9. Registran 4. Guideline 5. Study Title **Progress** Requirement Pattern Substance Frame Response Reports (Months) Number 0000 2 3 Density K, D, M, A, J, E, F, L 63-7 Solubility K, D, M, A, J, E, F, L 63-8 K, D, M, A, J, E, F, L Vapor Pressure 63-9 Dissociation Constant K, D, M, A, J, E, F, L 63-10 K, D, M, A, J, E, F, L Oct/Water partition Coef. 63-11 K, D, M, A, J, E, F, L βH 63-12 K, D, M, A, J, E, F, L 63-13 Stability K, D, M, A, J, E, F, L Flammability 63-15 Explodability K, D, M, A, J, E, F, L 63-16 K, D, M, A, J, E, F, L Storage stability 63-17 Viscosity K, D, M, A, J, E, F, L 63-18 K, D, M, A, J, E, F, L Miscibility 63-19 Initial to indicate certification as to information on this page Date 28

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number POLAR EQUIPMENT INC 3080 Iodine, Kl 04-Jan-1994 12881 FOOTHILL LANE Chemical # and Name 046905 **GENERIC** lodine SARATOGA, CA 95070 ID# GDCI-046905-17524 6. Use 7. Test 8. Time Guideline 5. Study Title 9. Registrant **Progress** ...quirement Pattern Substance Frame Response 0 Reports Number (Months) 0 0 2 3 K, D, M, A, J, E, F, L 63-20 Corrosion characteristics Dielectric breakdown voltage K, D, M, A, J, E, F, L 63-21 K, D, M, A, J, E, F, L 71-1a Acute avian oral quail/duck K, D, M, A, J, E, F, L 71-2a Acute avian diet, quail Fish toxicity rainbow trout K, D, M, A, J, E, F, L 72-1c K, D, M, A, J, E, F, L Invertebrate toxicity 72-2a Estu/mari tox. fish K, D, M, A, J, E, F, L За 72-3b Estu/mari tox. mollusk K, D, M, A, J, E, F, L K, D, M, A, J, E, F, L Estu/mari tox. shrimp 72-3c K, D, M, A, J, E, F, L Acute oral toxicity in rats 81-1 Acute dermal toxicity in rabbits or rats K, D, M, A, J, E, F, L 81-2 K, D, M, A, J, E, F, L 81-3 Acute inhalation toxicity in rats Initial to indicate certification as to information on this page Date 29 (full text of certification is on page one).

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.

1. Company Name and Address POLAR EQUIPMENT INC 12881 FOOTHILL LANE SARATOGA, CA 95070		Case # and Name 3080 lodine, Kl Chemical # and Name lodine	3080 lodine, Kl Chemical # and Name 046905					3. Date and Type of DCI and Number 04-Jan-1994 GENERIC ID # GDCI-046905-17524			
Guideline Requirement Number	5. Study Title		PROTOC	Pr R	ogre: eport	5\$ \$	6. Use Pattern		7. Test Substance	8. Time Frame (Months)	9. Registra Response
			O L	1	2	3					
81-4	Primary eye irritation in rabbits		N				K, D, M, A, J, E, F, L	-			
81-5	Primary dermal irritation		N				K, D, M, A, J, E, F, L	-			
81-6	Dermal sensitization		N				K, D, M, A, J, E, F, L	-			
82-3	90-day dermal-rodent		N				K, D, M, A, J, E, F, l	-			
82-4	90-day inhalrat		N				K, D, M, A, J, E, F, L	-			
82-1a	90-day feeding-rodent		N				K, D, M, A, J, E, F, L	-			
82-1b	90-day feeding-nonrodent		N				K, D, M, A, J, E, F, L	-			
83-4	2-generation reprorat		N				K, D, M, A, J, E, F, L	-			
33-1a	Chronic tox-rodent		N				K, D, M, A, J, E, F, L	-			
33-1b	Chronic tox - non-rodent		N				K, D, M, A, J, E, F, L	-			
B3-2a	Oncogenicity - rat		N				K, D, M, A, J, E, F, L	-			
B3-2b	Oncogenicity-mouse		Z				K, D, M, A, J, E, F, L	-			
nitial to indicate certif	fication as to information on this page n is on page one).								Date	<u> </u>	30

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number POLAR EQUIPMENT INC 3080 lodine, KI 04-Jan-1994 12881 FOOTHILL LANE Chemical # and Name 046905 **GENERIC** ladine SARATOGA, CA 95070 ID# GDCI-046905-17524 Guideline 6. Use 5. Study Title 7. Test 8. Time 9. Registrant Progress _quirement Pattern Substance Frame Response Reports Number (Months) COL 2 3 K, D, M, A, J, E, F, L Teratogenicity - rat N 83-3a K, D, M, A, J, E, F, L 83-3b Teratogenicity - rabbit Other genotoxic effects K, D, M, A, J, E, F, L 84-4 Gene mutation-ames 84-2a K, D, M, A, J, E, F, L 84-2b Struct. chrom. aberration K, D, M, A, J, E, F, L General metabolism K, D, M, A, J, E, F, L 85-1 Dermal penetration K, D, M, A, J, E, F, L 2 133-3 Dermal passive dosimetry expo K, D, M, A, J, E, F, L 133-4 Inhal, passive dosimetry expo-K, D, M, A, J, E, F, L Chemical identity K, D, M, A, J, E, F, L 160-5 171-2 Chemical identity K, D, M, A, J, E, F, L Directions for use K, D, M, A, J, E, F, L 171-3 Initial to indicate certification as to information on this page Date 31 (full text of certification is on page one).

OMB Approval 2070-174

United States Environmental Protection Agency Washington, D.C. 20460

RECHIREMENTS STATUS AND REGISTRANT'S RESPONSE

ты фалгорал	J. D. L.	
INSTRUCTIONS: Please type or print in ink. Please read car Use additional sheet(s) if necessary.	efully the attached instructions and supply the information requ	ested on this form.
Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
POLAR EQUIPMENT INC	3080 lodine, Kl	04-Jan-1994
12881 FOOTHILL LANE	Chemical # and Name 046905	GENERIC

SARATOGA, CA 950	070	lodine						ID# GDCI-046905-17524				
Guideline .quirement Number	5. Study Title		P R O T O C	Pro Re	ogres eport	ss s	6. Use Pattern		7. Test Substance	8. Time Frame (Months)	9. Registrant Response	
			L	1	2	3					!	
					ı	'						
61-1	Chemical Identity		N				K, D, M, A, J, E, F, L	-			!	
61-2a	Begin, mat. & mnfg, proc		N				K, D, M, A, J, E, F, L	-				
61-2b	Discussion of Impurities		N				K, D, M, A, J, E, F, L	-				
62-1	Preliminary Analysis	;	N				K, D, M, A, J, E, F, L	-				
62-2	Certification of limits		N				K, D, M, A, J, E, F, L	-				
3	Analytical Method		N				K, D, M, A, J, E, F, L	-		i		
63-2	Color		N				K, D, M, A, J, E, F, L	-				
63-3	Physical State		N				K, D, M, A, J, E, F, L	-			:	
63-4	Odor		N	ĺ	j		K, D, M, A, J, E, F, L	-				
63-5	Melting Point		N				K, D, M, A, J, E, F, L	-				
63-6	Bailing Paint		N				K, D, M, A, J, E, F, L	.				

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law

Signature and Title of Company's Authorized Representative_

12. Name of Company

13. Phone Number

11. Date

32

RECHIDEMENTS STATUS AND DECISTRANT'S RESPONSE

OMB Approval 2070-174

	REQUIREMENTS	STATUS AND REGIS	3 I E	A	(1.8	KI	SPUNSE			<u> </u>	
INSTRUCTIONS: Please tyl Use additional sheet(s) if neo	pe or print in ink. Please read carefully the cessary.	ne attached instructions and	supp	oly th	e info	rmai	tion requested on this for	m.			
1. Company Name and Address POLAR EQUIPMENT INC 12881 FOOTHILL LANE SARATOGA, CA 95070		Case # and Name 3080 lodine, KI Chemical # and Name lodine		046	905			Date and Type of DCI and Number 04-Jan-1994 GENERIC ID # GDCI-046905-17524			
4. Guideline Requirement Number	5. Study Title		PROTOCOL		ogres eport		6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registran' Response	
63-7	Density		Ν				K, D, M, A, J, E, F, L				
63-8	Solubility		N				K, D, M, A, J, E, F, L				
63-9	Vapor Pressure		N				K, D, M, A, J, E, F, L				
63-10	Dissociation Constant		N				K, D, M, A, J, E, F, L				
63-11	Oct/Water partition Coef.		N				K, D, M, A, J, E, F, L			1	
63-12	рН		N				K, D, M, A, J, E, F, L				
63-13	Stability		N				K, D, M, A, J, E, F, L			l '	
63-15	Flammability		N				K, D, M, A, J, E, F, L				
63-16	Explodability		N				K, D, M, A, J, E, F, L				
63-17	Storage stability		N				K, D, M, A, J, E, F, L				
63-18	Viscosity		N				K, D, M, A, J, E, F, L				
63-19	Miscibility		N				K, D, M, A, J, E, F, L				
Initial to indicate certification (full text of certification is on	as to information on this page		Ш					Date		33	

(full text of certification is on page one).

OMB Approval 2070-174

United States Environmental Protection Agency Washington, D.C. 20460

Agency Washington, D.C. 20460

	REQUIREMENTS:	STATUS AND REGIS	STI	RAN	YT'S	S RI	ESPONSE				
INSTRUCTIONS: Please typ Use additional sheet(s) if neo	pe or print in ink. Please read carefully the cassary.	ne attached instructions and	sup	oly th	e info	огта	tion requested on this fo	rm.		.1.	
1. Company Name and Add POLAR EQUIPMENT 12881 FOOTHILL LAI SARATOGA, CA 950	INC NE	Case # and Name 3080 lodine, Kl Chemical # and Name lodine		046	905				Date and Type of DCI and Nu 04-Jan-1994 GENERIC ID# GDCI-046905-17524		
Guideline ⊎quirement Number	5. Study Title		PROTOCO		ogre:		6. Use Pattern		7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			ĭ	1	2	3					
63-20	Corrosion characteristics		N				K, D, M, A, J, E, F, L	•			
63-21	Dielectric breakdown voltage		N				K, D, M, A, J, E, F, L				
71-1a	Acute avian oral quail/duck		N				K, D, M, A, J, E, F, L				
71-2a	Acute avian diet, quail		N				K, D, M, A, J, E, F, L	ı			
72-1c	Fish toxicity rainbow trout		N				K, D, M, A, J, E, F, L				
72-2a	Invertebrate toxicity		N				K, D, M, A, J, E, F, L	·			
3а	Estu/mari tox. fish		N				K, D, M, A, J, E, F, L				
72-3b	Estu/mari tox. mollusk		N				K, D, M, A, J, E, F, L	.			
72-3c	Estu/mari tox. shrimp		N				K, D, M, A, J, E, F, L				
81-1	Acute oral toxicity in rats		N				K, D, M, A, J, E, F, L				
81-2	Acute dermal toxicity in rabbits or rats		N				K, D, M, A, J, E, F, L				
81-3	Acute inhalation toxicity in rats		N				K, D, M, A, J, E, F, L				
Initial to indicate certification (full text of certification is on	Las to information on this page page one).	·					<u> </u>		Date	3	4

	REQUIREMENTS	STATUS AND REGI	STI	RAI	NT'S	S RI	ESPONSE					
INSTRUCTIONS: Please ty Use additional sheet(s) if ne	rpe or print in ink. Please read carefully cessary.	the attached instructions and	sup	ply th	e info	orma	tion requested on this f	orm.				
1. Company Name and Ad- POLAR EQUIPMENT 12881 FOOTHILL LA SARATOGA, CA 95	INC NE	Case # and Name 3080 lodine, KI Chemical # and Name lodine		046	905			3.	Date and Type of DCI an 04-Jan-1994 GENERIC ID # GDCI-046905-1			
4. Guideline Requirement Number	5. Study Title		PROTOCOL	Reports		ss ls	6. Use Pattern		7. Test Substance	8. Ti Fram (Mon	ne	9. Registrant Response
31-4	Primary eye irritation in rabbits			\vdash			K, D, M, A, J, E, F, I	L				
31-5	Primary dermal irritation		N				K, D, M, A, J, E, F, I	L				!
31-6	Dermal sensitization		N				K, D, M, A, J, E, F, I	L				
32-3	90-day dermal-rodent 90-day inhalrat						K, D, M, A, J, E, F, I	L				
32-4							K, D, M, A, J, E, F, I	L				
32-1a	90-day feeding-rodent		N				K, D, M, A, J, E, F, I	L				
3 2 -1b	90-day feeding-nonrodent		N				K, D, M, A, J, E, F, I	L				
33-4	2-generation reprorat		N				K, D, M, A, J, E, F, I	L				
33-1a	Chronic tox-rodent		N				K, D, M, A, J, E, F, I	L				
33-1b	Chronic tox - non-rodent		N				K, D, M, A, J, E, F, I	L				
33-2a	Oncogenicity - rat		N				K, D, M, A, J, E, F, I	L				
33-2b	Oncogenicity-mouse		N				K, D, M, A, J, E, F, I	L				
nitial to indicate certification as to information on this page full text of certification is on page one).									Date			35

OMB Approval 2070-174

United States Environmental Protection

Agency Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

Company Name and A	Address	2. Case # and Name 3						Date and Type of DCI and Number		
POLAR EQUIPMEN 12881 FOOTHILL L SARATOGA, CA	3080 Iodine, KI Chemical # and Name 046905 Iodine						04-Jan-1994 GENERIC ID# GDCI-046905-17524			
Guideline .quirement Number	5. Study Title		P R O T O C O L	Progres Report		ss ts	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			ľ۱	1	2	3				
83-3a	Teratogenicity - rat		И				K, D, M, A, J, E, F, L			
83-3b	Teratogenicity - rabbit		N				K, D, M, A, J, E, F, L			
84-4	Other genotoxic effects		N				K, D, M, A, J, E, F, L			
84-2a	Gene mutation-ames		N				K, D, M, A, J, E, F, L			
84-2b	Struct. chrom. aberration		N				K, D, M, A, J, E, F, L			
85-1	General metabolism		N				K, D, M, A, J, E, F, L			
2	Dermal penetration		N				K, D, M, A, J, E, F, L			
133-3	Dermal passive dosimetry expo		N			ľ	K, D, M, A, J, E, F, L			
133-4	Inhal, passive dosimetry expo		N				K, D, M, A, J, E, F, L			
160-5	Chemical identity		N				K, D, M, A, J, E, F, L			
171-2	Chemical identity		N				K, D, M, A, J, E, F, L			i
171-3	Directions for use		N				K, D, M, A, J, E, F, L			
Initial to indicate certification as to information on this page (full text of certification is on page one).								Date	<u> </u>	<u>. </u>

United States Environmental Protection Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 3080, lodine, KI

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
50233	POLAR EQUIPMENT INC		12881 FOOTHILL LANE	SARATOGA	CA 95070
1677	ECOLAB INC.		370 NORTH WABASHA STREET	ST. PAUL	MN 55102
15118	BALTIMORE AIRCOIL COMPANY INC	DELTA ANALYTICAL CORP	7910 WQODMONT AVE STE 1000	BETHESDA	MD 20814
47371	H & S CHEMICALS DIVISION		90 BOROLINE ROAD	ALLENDALE	NJ 07401
35217	HYBRID TECHNOLOGIES CORPORATION	REGWEST COMPANY, LLC	8203 WEST 20TH STREET, SUITE A	GREELEY	CO 806344696

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELI	VERY
■ Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired. ■ Print your name and address on the reverse so that we can return the card to you. ■ Attach this card to the back of the mailpiece, or on the front if space permits. 1. Article Addressed to: Robert Wallace Puke Equipment, Inc. 1299 Foothill Lane Saratoga, CA 9502-3712	D. Is delivery address different from item If YES, enter delivery address below 3. Service Type Certified Mail Express Mail	C. Pate of Delive
Re: 50233-1	4. Restricted Delivery? (Extra Fee)	☐ Yes
2. 7008 3230 0000 9481 1	989	

ror delivery inform	adji visit dal 1490	site at www.usps.come
Postage	\$	
Certified Fee		
Return Receipt Foe (Endorsement Required)		Postmark Here
Restricted Delivery Fee (Endorsement Required)		
Total Postage & Fees	\$	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

JUN 13 2013

Robert E. Wallace Polar Equipment, Inc. 12881 Foothill Lane Saratoga, CA 95070-3712

Subject: Polar Pure

EPA Registration Number: 50233-1 Letter Date: September 11, 2012

Dear Mr. Wallace:

The following label amendment submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable for the reason listed below:

I. <u>Proposed Amendment:</u>

- Add the word "Safe" to the product labeling;
- Add storage & disposal usage until use up stock of display boxes on hand is depleted.

II. Unacceptable Label Claims:

- 1. Under 40 CFR 156.10 (a) (5) (ix) label claims as to the safety of the pesticide or its ingredients are considered to be statements that are misbranding and thus are not allowed on pesticide labeling.
- 2. Regarding your request to update the storage and disposal statements for the subject product, the Agency's regulation requires that words, statements, graphic representations, designs or other information that are legally required to appear on a label be clearly legible, and readily understood. In addition, all required label text must appear on a clear contrasting background and not be obscured or crowded. Refer to 40 CFR 156.10(a) (2) for detailed information.

III. Other Information:

The Environmental Protection Agency completed its review of the available data on the antimicrobial iodine and iodophor complexes. The Reregistration Eligibility Decision

document (RED) was approved on July 27, 2006. A letter by Certified Mail was sent out to all registrant of pesticide products containing the active ingredient iodine and iodophor complexes.

The letter provided specific information on what registrant must do to maintain they products registration. It also provided the U. S. Federal Government website link for registrant to obtain copies of the RED and supporting documents for iodine and iodophor complexes. The website site is "www.regulations.gov. The docket identification number is EPA-HQ-OPP-2006-0599. This document also contains product-specific data that the agency required in Data Call-Ins (DCI). The DCI also contained pertinent instructions for complying with the iodine RED. For product-specific DCI (product chemistry, efficacy and acute toxicity data), the first set of required responses was due 90-days from the receipt of the DCI letter. The second set of required responses was due eight months from receipt of the DCI letter.

EPA has no record that you have complied/satisfied the conditions of the antimicrobial iodine and iodophor complexes RED and DCI. Please indicate whether you have responded to the RED and DCI within four (4) weeks from the date of this letter and provide documentation supporting your statements.

Should you have any questions or comments concerning this letter, please contact me via email at Mendelsohn.mike@epa.gov or by telephone at (703) 308-8715.

Sincerely, Marsho

Mike Mendelsohn

Acting Product Manager (32)

Regulatory Management Branch II

Antimicrobials Division (7510P)

Mendelsohn, Mike

From:

Polar Equipment [questions@polarequipment.com]

Sent:

Sunday, July 07, 2013 11:49 PM

To:

Mendelsohn, Mike

Subject:

Polar Pure iodine registration

Dear Mike,

You spoke with my father, Bob Wallace regarding the letter you sent to him of June 13, 2013 (original letter date Sept. 11, 2012) and our product Polar Pure EPA registration number 50233-1.

In section III (Other Information) of the above letter, you refer to the RED of July 27, 2006 and a certified letter that was sent to all registrants. Bob does not remember receiving a letter by certified mail in 2006 regarding this subject. I have checked the regulations website using the docket id number you refer to in the above letter but am not sure what forms are required.

Would you please reply to this e-mail and include a link to the exact form(s) and instructions that you require so that we can complete this part of the registration process.

Thank you, Ted Wallace, Polar Equipment, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

JUN 13 2013

Robert E. Wallace Polar Equipment, Inc. 12881 Foothill Lane Saratoga, CA 95070-3712

Subject:

Polar Pure

EPA Registration Number: 50233-1 Letter Date: September 11, 2012

Dear Mr. Wallace:

The following label amendment submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable for the reason listed below:

I. Proposed Amendment:

- Add the word "Safe" to the product labeling;
- Add storage & disposal usage until use up stock of display boxes on hand is depleted.

II. Unacceptable Label Claims:

- 1. Under 40 CFR 156.10 (a) (5) (ix) label claims as to the safety of the pesticide or its ingredients are considered to be statements that are misbranding and thus are not allowed on pesticide labeling.
- 2. Regarding your request to update the storage and disposal statements for the subject product, the Agency's regulation requires that words, statements, graphic representations, designs or other information that are legally required to appear on a label be clearly legible, and readily understood. In addition, all required label text must appear on a clear contrasting background and not be obscured or crowded. Refer to 40 CFR 156.10(a) (2) for detailed information.

III. Other Information:

The Environmental Protection Agency completed its review of the available data on the antimicrobial iodine and iodophor complexes. The Reregistration Eligibility Decision

document (RED) was approved on July 27, 2006. A letter by Certified Mail was sent out to all registrant of pesticide products containing the active ingredient iodine and iodophor complexes.

The letter provided specific information on what registrant must do to maintain they products registration. It also provided the U. S. Federal Government website link for registrant to obtain copies of the RED and supporting documents for iodine and iodophor complexes. The website site is "www.regulations.gov." The docket identification number is EPA-HQ-OPP-2006-0599. This document also contains product-specific data that the agency required in Data Call-Ins (DCI). The DCI also contained pertinent instructions for complying with the iodine RED. For product-specific DCI (product chemistry, efficacy and acute toxicity data), the first set of required responses was due 90-days from the receipt of the DCI letter. The second set of required responses was due eight months from receipt of the DCI letter.

EPA has no record that you have complied/satisfied the conditions of the antimicrobial iodine and iodophor complexes RED and DCI. Please indicate whether you have responded to the RED and DCI within four (4) weeks from the date of this letter and provide documentation supporting your statements.

Should you have any questions or comments concerning this letter, please contact me via email at Mendelsohn.mike@epa.gov or by telephone at (703) 308-8715.

Sincerely,

Mike Mendelsohn

mile mandedo

Acting Product Manager (32)

Regulatory Management Branch II Antimicrobials Division (7510P)



Fwd: Copy of the label
Ted and Laura Wallace to: Monisha Harris

01/09/2013 04:35 PM

Dear Monisha,

Please see below for copies of the box before and after changes you requested.

Thank you,

Ted Wallace, Polar Equipment, Inc.

Begin forwarded message:

From: Polar Equipment <questions@polarequipment.com>

Date: November 16, 2012 1:10:57 PM PST

To: Harris.Monisha@epamail.epa.gov

Bcc: Polar Equipment <questions@polarequipment.com>

Subject: Re: Copy of the label

Dear Monisha,

Attached are PDF files of the label as original and with the changes you request for the remainder of our inventory of boxes.

The word SAFE has been obscured

The disposal statement is as follows --

Storage and Disposal

Pesticide Storage: Store this product in its original container

Container Disposal: Non refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

Thank you,

Ted Wallace, Polar Equipment, Inc.



POF

polar pure box original018.pdf polar pure box change017.pdf

On Nov 16, 2012, at 10:56 AM, Harris Monisha@epamail.epa.gov wrote:

Please have Mr. Wallace send me a copy of his label which reflects the storage and disposal statement as well as the removal of the word safe via email (if you could provide assistance) please.

<16493415.gif>



Re: Copy of the label 🗋

Monisha Harris to: Polar Equipment

11/16/2012 04:58 PM

Would you please assist Mr. Wallace with filling out the application found here (http://www.epa.gov/opprd001/forms/8570-1.pdf) so we can conduct a label amendment on his label to ensure the wording is current. I will help you through this process.

Monisha Harris
US Environmental Protection Agency
Product Manager 32, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. MC 7510P
Washington, DC 20460

Physical Address One Potomac Yard 2777 Crystal Drive Adington, VA 22202 Phone: 703-308-0410



Polar Equipment

Dear Monisha, Attached are PDF files of the lab...

11/16/2012 04:13:20 PM

From:

Polar Equipment <questions@polarequipment.com>

To:

Monisha Harris/DC/USEPA/US@EPA

Date: Subject: 11/16/2012 04:13 PM Re: Copy of the label

Dear Monisha,

Attached are PDF files of the label as original and with the changes you request for the remainder of our inventory of boxes.

The word SAFE has been obscured

The disposal statement is as follows --

Storage and Disposal

Pesticide Storage: Store this product in its original container

Container Disposal: Non refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

Thank you,

Ted Wallace, Polar Equipment, Inc.

On Nov 16, 2012, at 10:56 AM, Harris.Monisha@epamail.epa.gov wrote:

Please have Mr. Wallace send me a copy of his label which reflects the storage and disposal statement as well as the removal of the word safe via email (if you could provide assistance) please.

<16493415.gif>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

October 24, 2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Robert Wallace 12881 Foothill Lane Saratoga, CA 95070-3712

Subject: EPA Reg. No. 50233-1

Polar Pure

Dear Mr. Wallace:

Thank you for your voice mail messages expressing concern with regards to the use of safety claims on antimicrobial product labeling. Your request in asking the Agency to amend its policy to allow the use of the term "safe" on product labeling cannot be approved. Under 40 CFR 156.10(a)(5)(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed," are false and misleading statements. Therefore, Agency regulations do not allow statements that contain the word safe or variations thereof to appear in pesticide labeling. Consequently, you must remove the word "safe" from your product if you intend to sale or market Polar Pure in any way.

Regarding the Storage and Disposal (S&D) statements that you have been asked to place on your box, I have included general storage and disposal statements that you can use on your product. You may place your S&D statement on the outside of your box, but if this is not possible, you may place your statement on the inside panel if clear instructions direct the reader to see the statements inside. Here is the link for more information on Storage and Disposal (http://www.epa.gov/oppfead1/labeling/lrm/chap-13.pdf). If you have additional questions, feel free to contact me.

Sincerely,

Monisha Harris Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure

Polar Equipment, Inc. • 12881 Footh... Lane • Saratoga, CA 95070 • (408) 88. J76 • www.polarequipment.com



Attn: Monisha Harris US EPA #1 Potomic Yard 2707 Crystal Dr. MC 7510 P Arlington, VA 22202

the state of the s
TO JOHN HARRIGAN, DIR
donni Pohun Pure Is not only BAFE,
IT IS "THUS MER!" PLENER WOTE
BROWEST FOR EXEMPTIONS WOULDLINE
YOUR OPINION. THANK, Bub wallow

September 11, 2012

Dear Monisha Harris,

Adam Heyward suggested I write to you regarding my request for an exemption to EPA requirements for changes to the display box for my product, Polar Pure Water Disinfectant for the reasons I recounted to him. You may recall, I discussed the same issue with you several months ago regarding removing the word "SAFE" from the Polar Pure box.

Polar Pure was intentionally designed to be "SAFE" for the following reasons.

- 1. A "particle trap" inside each Polar Pure bottle is designed to prevent any iodine crystals being displaced when decanting the saturated solution.
- 2. A liquid crystal thermometer is adhered to the bottle to provide uniform treatment dosage no matter what the concentration of the saturated solution.
- 3. Child protective cap is used.
- 4. The concentration of the iodine solution is only about 0.003%, or practically pure water. I have personally ingested the entire 2 oz. of the saturated solution with no ill effects. A normal thyroid contains about 10 mg. Iodine, the 2 oz of solution in the Polar Pure bottle contains about 18mg. of iodine. Any excess iodine consumed over 10 mg is expelled thru the kidneys. Polar Pure is entirely safe.
- 5. Iodine is probably the only material registered by EPA that is a benefit to the environment. Iodine is a necessary element in the body, the soil and water.
- 6. There also should be no concern about disposal of the empty bottle. In fact, if all the iodine in a new, full bottle of Polar Pure were to be dumped in the soil or water, this would be a boon to the environment. Hence, even the EPA's request to add the words proposed for disposing of the bottle are unnecessary.
- 7. If I am absolutely required to make changes on the box, it has been suggested by Joan Harrigan, Division Director, that I be allowed to use the 15,500 boxes (cost of \$4000) on hand, and make changes on the next order of boxes.

I request an exemption to leave the box as it is currently designed based on the above points. I would appreciate resolving this issue as soon as possible.

Sincerely,

Robert E Wallace, Polar Equipment, Inc.

1 Teb Mallace 1 (408) 773-9201

lease reed instructions on reverse before ct.	form.	Form Approv	od. / Yo. 2070	0-0060				
Environmental P Washingto	on, DC 20460		Registrati Amendme Other					
Application for Pesticide - Section I								
1. Company/Product Number POLAR EQUIPMENT 50233-	1	2. EPA Product Menag	57	3. Proposed Classification				
4. Company/Product (Name) POLAR EQUIPMENT / POLAR	PURE	PM# None Restricted						
5. Name and Address of Applicant (Include ZIP Code) POLAR EQUIPMENT 12881 Foothill Lane Saratoga, CA 95070 Check If this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No						
	Sec	tion - II						
X Amendment - Explain below. Resubmission in response to Agency letter det Notification - Explain below.	ied	Final printed labels in response to Agency letter dated "Me Too" Application. Other - Explain below.						
stock of display boxes on hand is depleted. Section - III								
1. Material This Product Will Be Packaged In:		7-144						
	No. per If "Yes	Yes		ype of Container Metal Plastic Glass Paper Other (Specify)				
3. Location of Net Contents Information 4.	Size(s) Retail Centai	ner 5	Location of Label On Label On Labeling	Directions g accompanying product				
6. Menner in Which Label is Affixed to Product	Lithograph Paper glued Stanciled	Other						
		ion - IV		······································				
1. Contact Point	identification of indivi	idual to be contacted, if	necessary, to proc	ess this application.)				
Name Robert E. Wallace	Title Pre	sident	7	elephone No. (Include Area Code) (408) 867-4576				
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or micloading statement may be punishable by fine or imprisonment or both under applicable law. 6. Date Application Received (Stampad)								
2. Signeture	3. Title							
4.Typed Name Robert E. Wallace	5. Date 1	1/26/2012						

EPA Form 8570-1 (Rev. 8-94) Previous editione are obsolete.

White - EPA File Copy (original)

Yellow - Applicant Copy

Ø 001

TRANSMISSION OK

TX/RX NO
CONNECTION TEL
SUBADDRESS

3800

914088674576

CONNECTION ID ST. TIME USAGE T PGS. RESULT

01/12 04:46 00'27 1 0K

Facsimile Transmission

TO: Mr. Bob Wallace

(Ph. 408-867-4576; FAX: 408-867-4576)

FROM: Killian Swift

(Ph. 703-308-6346; FAX: 703-308-8481)

Dear Bob:

Ms. Monisha Harris, Product Manager 32, reviewed and approved, as accurate, all of the information that I have sent to you by fax transmission.

You must bring your product label up to current EPA standards in order to be allowed to sell and distribute your product in United States channels of trade.

Product Manager 32, Monisha Harris will be happy to confirm for you what I am saying to you here.

If you believe that you need to discuss the issues with her. Ms. Harris may be contacted by telephone at 703-308-0410.

TO: Mr. Bob Wallace

(Ph. 408-867-4576; FAX: 408-867-4576)

FROM: Killian Swift

(Ph. 703-308-6346; FAX: 703-308-8481)

Dear Bob:

Ms. Monisha Harris, Product Manager 32, reviewed and approved, as accurate, all of the information that I have sent to you by fax transmission.

You must bring your product label up to current EPA standards in order to be allowed to sell and distribute your product in United States channels of trade.

Product Manager 32, Monisha Harris will be happy to confirm for you what I am saying to you here.

If you believe that you need to discuss the issues with her. Ms. Harris may be contacted by telephone at 703-308-0410.

Please be willing to comply with the information that we have provided to you in order to continue to distribute and sell your product.

Thank you, Mr. Wallace, for your attention.

Killian B. Swift 703-308-6346

TRANSMISSION OK

TX/RX NO CONNECTION TEL SUBADDRESS

3841

914088674576

CONNECTION ID ST. TIME USAGE T PGS. RESULT

02/09 02:39 00'24 1 0K

Facsimile Transmission

(Thursday, February 9, 2012)

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8481)

Bob, this is in response to your telephone Voice Mail message of Wednesday, February 8, 2012.

I have no new information to impart to you since you spoke with Regulatory Management Branch 2 Chief, Mr. Mark Alan Hartman.

I am not assigned to work on any submission from you at the present time.

If there is some new issue that you would like to open, then you need to contact Product Manager 32, Ms. Monisha Harris at 703-308-0410.

I hope that this information is a benefit to you.

(Thursday, February 9, 2012)

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8481)

Bob, this is in response to your telephone Voice Mail message of Wednesday, February 8, 2012.

I have no new information to impart to you since you spoke with Regulatory Management Branch 2 Chief, Mr. Mark Alan Hartman.

I am not assigned to work on any submission from you at the present time.

If there is some new issue that you would like to open, then you need to contact Product Manager 32, Ms. Monisha Harris at 703-308-0410.

I hope that this information is a benefit to you.

Killian Swift - 1:59 AM - Thursday - 02/09/2012

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8418)

Mr. Wallace, please contact Regulatory Management Branch II Chief, Mr. Mark Alan Hartman at 703-308-0734 to discuss your labeling issues with using the word "safe" on your product packaging as well as the issue of how to receive an updated EPA stamped accepted label for your old product, Polar Pure.

This is also is a good opportunity to discuss any issue you foresee as a problem in gaining an EPA registration for your proposed new product, Polar Pure Plus.

Once you and Mr. Hartman have discussed your issues thoroughly, Mr. Hartman will design a "plan or action" for Ms. Monisha Harris, Product Manager 32, and for Killian B. Swift, Product Reviewer, to follow to move you forward in your pesticide product registration processes.

Mr. Hartman will detail for you what the EPA is allowed to accept as a regulatory matter.

I hope this guidance benefits you.

Killian - 4:36 AM - Tuesday - 01/24/2012

(Thursday, January 26, 2012)

TO: Mr. Bob Watson

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8481)

Bob, this is in response to your most recent telephone message of 01/25/2012.

Regulatory Management Branch 2 Chief, Mr. Mark Alan Hartman has authority over Ms. Monisha Harris, Product Manager 32 as well as over Killian B. Swift, Product Reviewer.

Mr. Hartman has telephoned you to tell you that you are constrained by EPA labeling mandates from using the word "safe" on your pesticide product packaging.

If you do not choose to comply with the restriction that Mr. Hartman has placed on you, then you are subject to Enforcement Action by the Environmental Protection Agency.

I cannot tell you what penalty that will accrue to you, because I do not have that information.

Killian - 3:33 AM - Thursday - 01/26/2012 - 703-308-6346

TRANSMISSION OK

TX/RX NO CONNECTION TEL SUBADDRESS 3815 914088674576

SUBADDRESS CONNECTION ID

CONNECTION ID ST. TIME USAGE T PGS.

RESULT

01/25 03:39 03'15

0K

Facsimile Transmission

Wednesday, January 25, 2012

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8481)

FAX Transmission = Cover Sheet + 7-page Agency Letter

Mr. Wallace, Regulatory Management Branch 2 Chief, Mr. Mark Alan Hartman asked that I send you the following 7-page letter, dated January 2, 2006, regarding the use of the word "safe" on pesticide product labeling.

We hope that this information benefits you.

Wednesday, January 25, 2012

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8481)

FAX Transmission = Cover Sheet + 7-page Agency Letter

Mr. Wallace, Regulatory Management Branch 2 Chief, Mr. Mark Alan Hartman asked that I send you the following 7-page letter, dated January 2, 2006, regarding the use of the word "safe" on pesticide product labeling.

We hope that this information benefits you.

Killian – 2:59 AM – Wednesday – 01/25/2012

TRANSMISSION OK

TX/RX NO 3802

CONNECTION TEL 914088674576

SUBADDRESS CONNECTION ID

ST. TIME 01/17 04:49

 USAGE T
 00'25

 PGS.
 1

 RESULT
 0K

Facsimile Transmission

(January 17, 2012)

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian Swift

(Phone: 703-6546; FAX: 703-308-8481)

Dear Bob:

This represent my formal response to the voice mail that you left for me on Monday to tell me that I have not telephoned you.

I am aware that I have not telephoned you.

It is foolish to speak words that impart no further information.

There is absolutely nothing that I can say to you in a telephone call that will change or add to the information that I have sent to you in two fax transmissions.

The information that I already have sent to you by fax has been reviewed and approved as accurate and sufficient by your Product Manager, Ms. Monisha Harris.

If you do not choose to comply with the instructions that the EPA has provided you up to this point, then there is nothing more that EPA personnel can say to you by telephone that will move you forward out of the stuck position that your registrations currently are in.

Again if you doubt this information, then I welcome you to discuss this matter with your Product Manager, Ms. Monisha Harris.

(January 17, 2012)

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian Swift

(Phone: 703-6546; FAX: 703-308-8481)

Dear Bob:

This represent my formal response to the voice mail that you left for me on Monday to tell me that I have not telephoned you.

I am aware that I have not telephoned you.

It is foolish to speak words that impart no further information.

There is absolutely nothing that I can say to you in a telephone call that will change or add to the information that I have sent to you in two fax transmissions.

The information that I already have sent to you by fax has been reviewed and approved as accurate and sufficient by your Product Manager, Ms. Monisha Harris.

If you do not choose to comply with the instructions that the EPA has provided you up to this point, then there is nothing more that EPA personnel can say to you by telephone that will move you forward out of the stuck position that your registrations currently are in.

Again if you doubt this information, then I welcome you to discuss this matter with your Product Manager, Ms. Monisha Harris.

Ms. Harris may be reached by telephone at 703-308-0410.

Thank you, Mr. Wallace, for your attention.

Sincerely yours,

Killian B. Swift

TRANSMISSION OK

TX/RX NO CONNECTION

CONNECTION TEL

SUBADDRESS CONNECTION ID

ST. TIME USAGE T PGS.

RESULT

3813

914088674576

01/24 04:50

00'29 1 OK

Facsimile Transmission

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8418)

Mr. Wallace, I apologize that it has taken me this long to respond to you. The Voice Mail function on my telephone has been broken for more than a week, and it has been impossible for me to access my Voice Mail messages.

Mr. Wallace, it does not matter what mitigation measures you have employed in the packaging of your pesticide product. Current EPA regulation makes it illegal to use the word "safe" on pesticide product packaging intended to be sold and distributed in United States channels of trade.

One of the stuck places for your registered product Polar Pure is the need for the EPA to have an updated accepted product label in Agency files. This is why we updated your Polar Pure product label for you, so that it meets current EPA labeling standards.

If you accept the draft labeling update that we sent to you by fax. If you send that draft label to the Agency as your final product label along with an application for a labeling amendment request, then we will send back to you an EPA stamped accepted label.

Please be willing to use the draft labeling that we sent you by fax and intended as an update for Polar Pure as the appropriate model for the product labeling for your new, proposed registration for Polar Pure Plus.

V--- ---- and the Branch Chief Mr. Mark Alan Hartman at 703-308-0734.

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Killian B. Swift

(Phone: 703-308-6346; FAX: 703-308-8418)

Mr. Wallace, I apologize that it has taken me this long to respond to you. The Voice Mail function on my telephone has been broken for more than a week, and it has been impossible for me to access my Voice Mail messages.

Mr. Wallace, it does not matter what mitigation measures you have employed in the packaging of your pesticide product. Current EPA regulation makes it illegal to use the word "safe" on pesticide product packaging intended to be sold and distributed in United States channels of trade.

One of the stuck places for your registered product Polar Pure is the need for the EPA to have an updated accepted product label in Agency files. This is why we updated your Polar Pure product label for you, so that it meets current EPA labeling standards.

If you accept the draft labeling update that we sent to you by fax. If you send that draft label to the Agency as your final product label along with an application for a labeling amendment request, then we will send back to you an EPA stamped accepted label.

Please be willing to use the draft labeling that we sent you by fax and intended as an update for Polar Pure as the appropriate model for the product labeling for your new, proposed registration for Polar Pure Plus.

You may contact my Branch Chief, Mr. Mark Alan Hartman at 703-308-0734, if you believe it will help you move your registrations forward faster.

FACSIMILE TRANSMISSION

OK

Monday, January 9, 2012

TO: Mr. and Mrs. Bob Wallace

RESULT

(FAX: 408-867-4576)

FROM: Killian Swift

(Ph. 703-308-6346; FAX: 703-308-8481)

Dear Mr. and Mrs. Wallace:

Please read you the email message that I now am sending to you by fax. Please review the draft product labeling that the EPA has prepared for you for your current, registered product. If you choose to accept this draft labeling as your own product label, then label approval is extremely likely.

I understanding that you have another product that is pending a new product registration.

If you use the draft label that we are sending to you here as the model for the label for your pending product registration, then label acceptance is once again extremely likely.

I hope the information that the EPA is providing you here is beneficial to you both.

FACSIMILE TRANSMISSION

Monday, January 9, 2012

TO: Mr. and Mrs. Bob Wallace

(FAX: 408-867-4576)

FROM: Killian Swift

(Ph. 703-308-6346; FAX: 703-308-8481)

Dear Mr. and Mrs. Wallace:

Please read you the email message that I now am sending to you by fax. Please review the draft product labeling that the EPA has prepared for you for your current, registered product. If you choose to accept this draft labeling as your own product label, then label approval is extremely likely.

I understanding that you have another product that is pending a new product registration.

If you use the draft label that we are sending to you here as the model for the label for your pending product registration, then label acceptance is once again extremely likely.

I hope the information that the EPA is providing you here is beneficial to you both.

Sincerely yours,

Killian B. Swift

703-308-6346

FAX: 703-308-6346

Email: swift.killian@epa.gov

<u>To</u>: Cc: marj@yahoo.com, swift.killian@epa.gov,

00.

Monisha Harris/DC/USEPA/US, Killian Swift/DC/USEPA/US,

عوري والرواز والمراوي والمعاري والمعارية والمعارية والمعارية والمعارية والمعارية والمعارية والمعارية

Bcc:

Subject: EPA Reg.No. 50233-2 Polar Pure Plus Disinfectant



Dear Mr. Bob Wallace:

The product **Polar Pure Plus Water Disinfectant** (EPA Reg. No. 50233-2) was registered for sale and distribution in the United States many, many years ago.

The registration standards for pesticide product labeling and packaging have changed since your product first became available for distribution and sale in the United States.

Before we proceed to the revisions that must be made to your product labeling, please know that it is not acceptable to have the word "Safe" printed on your pesticide product packaging.

You must delete the word "Safe" from any pesticide product packaging that is put into channels of trade for distribution and sale in the United States.

Your Product Manager now is Ms. Monisha Harris, Product Manager 32.

You may contact Monisha Harris by telephone at 703-308-0410.

you may contact Monisha Harris by email at harris.monisha@epa.gov.

We understand that bringing a very old pesticide product label up to current EPA standards can be a difficult undertaking.

Therefore to be as helpful to you as we can be, EPA personnel has updated to current EPA standards your product label for **Polar Pure Plus Water Disinfectant** (EPA Reg. No. 50233-2).

If you will accept the draft labeling that EPA has prepared for you along with your application form stating that you are submitted revised product label in order to receive a new EPA stamped approved label, then it is very likely that such an application will be approved and you will receive your new stamped approved.

111_50233-2_POLAR PURE PLU1_ Agency Revised Label.docx

Please know that you need to use this label as the model for your other products. the idea is to draft your labels as similar in format as possible, taking under consideration of course the unique purpose of the product.

Thank you, Mr. Wallace!

Killian Swift 703-308-6346 swift.killian@epa.gov

Contractor:

Please be willing to add the information underneath this Note to the permanent Regulatory File Jacket for **EPA Reg. No. 50233-1.**

"Borrow Jackets" tells me that the existing File Jacket for **EPA Reg. No. 50233-1** has been "Imaged."

Thank you in advance for your help with this issue!

Killian B. Swift - Wednesday - 1:44 AM - October 31, 2012

U. S. EPA Facsimile Transmission:

TO: Mr. Bob Wallace

(Phone: 408-867-4576; FAX: 408-867-4576)

FROM: Mrs. Monisha Harris, EPA Product Manager 32

(Phone: 703-308-0410; FAX: 703-308-8481)

FAX Transmission = Cover Page + 3-page Agency Letter:

Dear Mr. Wallace:

Please find attached a 3-page EPA Agency Letter addressed to you -- drafted in order to be responsive to your Voice Mail messages.

This Agency Letter also is intended to provide you with the Regulatory Guidance that the U.S. EPA is required to follow regarding labeling that involves a claim of "safety."

We hope that you find this Agency Letter and the information contained therein beneficial in explaining U. S. EPA regulatory constraints.

Killian B. Swift – Thursday – 11:14 AM – October 25, 2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

October 24, 2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. Robert Wallace 12881 Foothill Lane Saratoga, CA 95070-3712

Subject: EPA Reg. No. 50233-1

Polar Pure

Dear Mr. Wallace:

Thank you for your voice mail messages expressing concern with regard to the use of safety claims on antimicrobial product labeling. Your request that the Agency amend its policy to allow the use of the term "safe" on product labeling cannot be approved. Under 40 CFR 156.10(a)(5)(ix), claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" are false or misleading statements. Therefore, Agency regulations do not allow statements that contain the word "safe" or variations thereof to appear in pesticide labeling. Consequently, you must remove the word "safe" from your product if you intend to sell or distribute Polar Pure.

Regarding the Storage and Disposal (S&D) statements that you have been asked to place on your box, I have included general storage and disposal statements that you can use on your product. You may place your S&D statement on the outside of your box, but if this is not possible, you may place your S&D statement on the inside panel, if clear instructions refer the reader to the statements inside. Here is the link for more information on Storage and Disposal (http://www.epa.gov/oppfead1/labcling/lrm/chap-13.pdf). If you have additional questions, feel free to contact me.

Sincerely

Monisha Harris

Product Manager 32

Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure

D. Type Size Requirements

The heading "Storage and Disposal" must be in type of the same minimum sizes as required for the child hazard warning by 40 CFR 156.60(b). (See §156.10(i)(2)(ix))

III. General storage and disposal statements

The Agency historically has required the following sentence for non-residential/household use products:

"Do not contaminate water, food, or feed by storage and disposal".

Preferably, registrants should place this statement immediately under the heading "Storage and Disposal" since it concerns both storage and disposal. However, it may be placed elsewhere within the Storage and Disposal section. (See PR Notice 83-3)

IV. Pesticide storage statements

Registrants must have instructions for proper storage of pesticide products. (§156.10(i)(2)(ix)) Safe storage is essential to protect against accidental exposure to children, bystanders and workers, environmental contamination due to leaks and spills, and intentional exposure due to vandalism or terrorism. EPA has preferred storage instructions for certain active ingredients (Section A); suggested statements for other products (Section B); and guidelines for registrants developing their own storage instructions (Section C).

A. Preferred Storage Statements (for products with certain active ingredients)

As mentioned above, the Agency has preferred storage statements for products with the following active ingredients:

- Calcium hypochlorite liquid and solid
- Chloropicrin
- Ethylene oxide
- Etridiazole
- Sodium hypochlorite liquid
- Sulfuryl fluoride
- Methyl bromide and methyl bromide plus 2% or less ehloropicrin
- Phosphide aluminum and magnesium
- Sodium cyanide

For products with one of these active ingredients, see Attachment A for the appropriate storage statement(s).

B. Suggested Storage Statements (for products with active ingredients not included in the list above)

A list of EPA-suggested storage statements for all other products (not listed above in A) is provided in Attachment B.

ATTACHMENT B

Storage Statements Suggested by EPA

The following are examples of storage statements that registrants may use for products with active ingredients not listed in *Attachment A*. EPA provided these suggested statements as a result of a recommendation from the State FIFRA Issues Research and Evaluation Group. Some of these may not be appropriate for all pesticide products.

"Always store pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents."

"Storage areas must be locked and secure from vandalism, with precautionary signs posted."

"The storage area must be dry, well-lit, and well-ventilated. Keep pesticide storage areas clean. Clean up any spills promptly."

"Store pesticides away from food, pet food, feed, seed, fertilizers, and veterinary supplies."

"Protect pesticide containers from extreme heat and cold."

"Store herbicides, insecticides and fungicides in separate areas within the storage unit."

"Place liquid formulations on lower shelves and dry formulations above."

"Maintaining a spill kit and fire extinguisher on hand and having emergency phone numbers posted will allow you to be prepared for emergencies."

"If spill cleanup PPE is stored nearby, but outside the pesticide storage area, it will be accessible when needed."